UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): December 9, 2020

EVELO BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38473**	**46-5594527**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

620 Memorial Drive
Cambridge, Massachusetts 02139
(Address of principal executive offices) (Zip Code)

(617) 577-0300
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	EVLO	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

Evelo Biosciences, Inc. (the "Company") recently updated its business information as follows:

Phase 1/2 Clinical Trial of EDP1503 in Combination with Pembrolizumab

On December 9, 2020, the Company announced that additional interim clinical data from its Phase 1/2 open-label study evaluating EDP1503 in combination with pembrolizumab in patients with triple-negative breast cancer were presented in a poster session at the San Antonio Breast Cancer Symposium 2020 Virtual Meeting. As of the data cutoff date of October 30, 2020, 15 patients had been treated across two EDP1503 doses, including three patients treated with low dose EDP1503 (two capsules twice daily ("BID")) and 12 patients treated with high dose EDP1503 (four capsules BID). 27% of patients had received prior anti-PD-(L)1 therapy.

Interim Safety Results – As of the cutoff date, the combination of EDP1503 and pembrolizumab was generally well-tolerated with the majority of treatment-related adverse events ("AEs") reported by investigators being Grade 1 or 2. Across all grades, treatment-related AEs reported by investigators most commonly included abdominal distension (20%), decreased appetite (20%), diarrhea (13%), flatulence (13%), nausea (13%), pruritis (13%) and rash maculo-papular (13%). Investigators reported a single treatment-related Grade 3 AE in one patient (diarrhea). No treatment-related Grade 4 or 5 AEs or serious AEs were reported, and one patient discontinued EDP1503 due to a treatment-related AE.

Interim Efficacy Results – Fifteen patients were evaluable for response assessment as of the cutoff date, as measured using the Response Evaluation Criteria in Solid Tumors (RECIST). Among all 15 patients treated, the overall response rate ("ORR") was 13 percent, and the disease control rate ("DCR") was 20 percent. In patients receiving high dose EDP1503 therapy, the ORR was 17 percent and the DCR was 25 percent, with partial responses observed in two patients and stable disease observed in one patient. One patient who had relapsed on prior therapy with an anti-PD-L1 inhibitor combination had a partial response to the EDP1503 and pembrolizumab combination treatment. The patient was on treatment for 10.5 months and had no measurable disease visible on their latest PET scan as of the data cutoff date.

Prioritization of EDP1908

The Company previously announced preclinical data for EDP1908, its bacterial extracellular vesicle (EV) product candidate for the treatment of cancer, were presented at the Society for Immunotherapy of Cancer virtual meeting in November 2020. In the preclinical study, tumor-bearing mice were treated with ascending doses of either oral EDP1908 or the parental microbial strain of EDP1908, or with anti-PD-1. The data demonstrated that treatment with EDP1908 resulted in superior tumor inhibition versus either the parent microbial strain or anti-PD-1 therapy, with an observed dose-dependent reduction in tumor growth.

The data also demonstrated that treatment with EDP1908 activated IFNγ-positive cytolytic and helper lymphocytes, dendritic cells, and interferon gamma-induced protein 10 (IP-10) in the tumor microenvironment. Fluorescent biodistribution analysis showed that EDP1908 was not detected outside the gastrointestinal tract. These data suggest that EDP1908 activated innate immunity locally on host immune cells in the gut and triggered distal immune responses within the tumor microenvironment, with no apparent adverse safety or tolerability issues.

Following a comprehensive assessment of the EDP1503 data and informed by the foregoing, the Company has determined to prioritize the development of EDP1908 as its lead clinical candidate in oncology given its superior preclinical activity over EDP1503. The Company is scaling up manufacturing in order to advance EDP1908 into the clinic in the first half of 2022. The Company will halt patient recruitment in the Phase 1/2 clinical trial of EDP1503 and will wind down the study.

Positive Topline Clinical Data in Phase 1b Trial of EDP1815 in Atopic Dermatitis

On December 9, 2020, the Company reported positive topline clinical data from its Phase 1b clinical trial of EDP 1815 in 23 evaluable subjects with mild to moderate atopic dermatitis. The primary endpoint of the Phase 1b trial was safety and tolerability. EDP1815 was observed to be well tolerated with no serious adverse events.

Secondary Endpoints – Secondary endpoints included a range of established markers of clinical efficacy in atopic dermatitis, such as the percentage change in Eczema Area and Severity Index ("EASI") score, which is the most common tool used to measure extent and severity of atopic eczema, and the percentage change in Investigator's Global Assessment and Body Surface Area ("IGA* BSA"). Clinical differences between EDP1815 and placebo for evaluable subjects were statistically significant at day 56 in both the percentage change in EASI (62% difference, p=0.034) and the percentage change in IGA*BSA (71% difference, p=0.019). Improvements in these measures were observed as early as day 14. At day 56, 10/16 patients in the active group showed improvements in EASI score, with 4/16 patients having achieved an EASI50 clinical response, 3 of which achieved at least an EASI75, compared to 0/7 of patients in the placebo group. These results provide further evidence that modulating SINTAX can drive significant clinical benefit without the need for systemic exposure. The Company intends to advance EDP1815 into later-stage trials in atopic dermatitis.

About the EDP1815 Phase 1b Clinical Trial – EDP1815-101 is a double-blind, placebo-controlled Phase 1b trial designed to evaluate the safety and tolerability of EDP1815 in healthy volunteers and patients with psoriasis or atopic dermatitis. The atopic dermatitis cohort enrolled 24 patients with mild to moderate atopic dermatitis, randomized 2:1 to receive oral administration of the enteric capsule formulation of EDP1815 or placebo once daily, for 56 days. As of December 1, 2020, 23 patients had reached the day 56 analysis, including all 16 patients in the treatment group and 7/8 patients in the placebo group. Patients were not allowed to use active topical treatments and were not required to use emollients. Efficacy data provided is for 23 of the 24 patients in the study; safety data provided is for all 24 patients. The primary endpoint was safety and tolerability. Secondary endpoints included a range of established markers of atopic dermatitis. The full clinical data set, including final subject visits, blood biomarkers, and the SCORAD, POEM and DLQI scores, will be analyzed and reported in early 2021.

Forward-Looking Statements

This Current Report on Form 8-K (the "Current Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements concerning the development of EDP1908 and EDP1815, the promise and potential impact of EDP1908 and the Company's other product candidates, the timing of and plans for clinical trials of EDP1908, and the future results for the Phase 1b clinical trial of EDP1815.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the impact of the COVID-19 pandemic on the Company's operations, including the Company's preclinical studies and clinical trials, and the continuity of the Company's business; the Company has incurred significant losses, is not currently profitable and may never become profitable; the Company's need for additional funding; the Company's limited operating history; the Company's unproven approach to therapeutic intervention; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; the Company's reliance on third parties and collaborators to expand its microbial library, conduct its clinical trials, manufacture its product candidates, and develop and commercialize its product candidates, if approved; the Company's lack of experience in manufacturing, selling, marketing, and distributing its product candidates; failure to compete successfully against other drug companies; protection of the Company's proprietary technology and the confidentiality of its trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of its intellectual property; the Company's patents being found invalid or unenforceable; risks associated with international operations; the Company's ability to retain key personnel and to manage its growth; the potential volatility of the Company's common stock; the Company's management and principal stockholders have the ability to control or significantly influence its business; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against the Company. These and other important factors discussed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, as may be updated in the Company's other filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While the Company may elect to update such forward-looking statements at some point in the future, except as required by law, the Company disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EVELO BIOSCIENCES, INC.

Date: December 9, 2020

By: /s/ Daniel S. Char
Daniel S. Char
General Counsel & Secretary